

New and Enhanced Conflict of Interest Principles

The following Board-approved principles strengthen, and in some cases clarify, Memorial Sloan Kettering's (MSK) Conflict of Interest (COI) and Conflict of Commitment (COC) policies. Actual and perceived conflicts of interest are intrinsic to the industry collaborations required to advance novel treatments in cancer care. These approved principles – adopted by the Executive Committee of the MSK Board of Managers on April 3, 2019 – address whether and how the institution will permit, disclose, and manage outside interests and relationships (involving both the institution and Covered Persons) in the context of preserving and protecting MSK's commitment to its mission and community.

These approved principles must be understood in the context of MSK's core mission: a commitment to advancing cancer care through scientific discovery. In alignment with this mission, our research community is developing novel concepts and treatments in cancer care and prevention. In order to translate this innovative research into treatments that can be made available to patients everywhere, MSK, as a nonprofit organization, must work with industry partners who have the necessary resources and expertise to commercialize these products.

Federal law allows and promotes the transfer of ideas from the nonprofit to the for-profit sector in this way; researchers and research institutions invent diagnostics, treatments, therapies, and products, and have intellectual property rights to these inventions. Conflicts of interest are unavoidable in the transfer of intellectual property from MSK to the for-profit sector that is required for further development, and so MSK must balance promoting innovation with ensuring the integrity of its clinical care, research, and education missions.

MSK's mission and obligations to its patients, research participants, staff members, students, trainees, and larger community must be the primary driver for institutional decisions about interactions with industry. This principle applies to MSK as an institution and to each member of the MSK staff. Potential financial benefits must not influence judgment or decision-making by MSK or MSK staff. When addressing conflicts of interest in research, protecting the rights and welfare of those who participate in our research and the integrity of our research activities is paramount.

The approved principles will guide the MSK Board and staff in enhancing its conflicts management program, adapting to a continuously changing environment, and improving oversight as the institution pursues vital collaborations with the larger cancer community to advance treatments for patients.

These approved principles reflect months of thoughtful discussion led by the Conflict of Interest Task Force. These principles are further supplemented by input from four additional workstreams: a focused review of external activities by Debevoise & Plimpton; a benchmarking survey of academic medical centers by Ropes & Gray; an

audit of MSK's COI program capabilities by Deloitte; and engagement with internal and external stakeholders, including patients, medical staff, SKI faculty, senior leadership, and nursing. They build on already-approved Board action:

- **Senior Executives:** Senior Executive Officers at MSK are not permitted to serve on the boards of directors of external for-profit health- or life science-related entities.
- **MSK Spin-offs:** MSK's Office of Technology Development will assess whether MSK will have a governance role in an MSK spin-off company and will not presume that MSK will have a voting seat on the board. Any compensation related to an employee serving on the board of a spin-off at the request and on behalf of MSK must be paid to MSK. To the extent that an MSK employee receives equity in an MSK spin-off company, that financial interest must be disclosed to, and reviewed by, the Conflicts of Interest Committee (COIC).
- **MSK Board Members:** Members of MSK's Board are not permitted to invest in or serve as either a board member or an executive officer of an MSK spin-off.

Overview of Board-Approved Principles:

1. **Governance and Oversight:** The principles call on the institution and MSK's Board to take a more active role in the review and oversight of COIs and COCs.
 - **Formalization of Board Role:** The Board's role in the oversight of conflicts-related issues will be formalized in a manner designed to ensure that the Board is actively engaged in overseeing the implementation of, and compliance with, MSK's conflicts-related policies and procedures, consistent with MSK's bylaws.
 - **Board Reputational Management:** The Board will actively consider the reputational ramifications of institutional and Covered Person conflicts. This includes consideration of issues such as the perception of potential conflicts and the risk of attendant reputational damage to MSK.
 - **Board-Level Committee:** MSK will establish a Board Committee charged with responsibility for oversight of conflicts management for all employees, Board members, and MSK as an institution (Board COI Committee). The Board COI Committee's review of conflicts-related matters will be appropriately documented.
 - **Board-Level Monitoring:** The Board COI Committee will develop mechanisms to ensure that MSK has implemented an effective conflicts management program. This includes reviewing relevant data and performance metrics, and periodically meeting with personnel responsible for conflicts management to ensure that systems and processes are functioning

appropriately and that sufficient resources are available. More formal and frequent review of Senior Executive Officers' financial interests will also enable the Board COI Committee to more effectively oversee compliance with MSK policies.

- **Board-Level Conflicts:** The Board COI Committee will review and enhance the processes for vetting and managing conflicts involving fellow Board members, including establishing a mechanism to ensure that management plans are implemented in appropriate circumstances. In addition, the Board COI Committee will undertake a review of ongoing relationships.
 - **Board-Commissioned Effectiveness Reviews:** The Board COI Committee will consider commissioning an effectiveness review of MSK's conflicts program every two to three years to ensure that policies and procedures remain effective and reflect best practices.
 - **Consolidation of Conflicts Policies and Procedures:** At the management level, MSK will consolidate conflicts review procedures for all employees under one function with appropriate expertise and resources. Conflicts for all employees will be reviewed pursuant to a common set of standards and procedures under the direction of the COIC and with appropriate Board oversight. MSK's conflicts policies will be harmonized and simplified in a more reader-friendly format, and a review will be conducted to ensure that the provisions in the policies are achievable. MSK Compliance and the COIC will also ensure that all procedures set out in MSK's conflicts policies are implemented and that Covered Persons (including Board members) are appropriately and effectively trained on MSK's conflicts policies.
 - **New Employee Pre-Clearance:** MSK will implement a mechanism to ensure that proposed new employees' financial interests are vetted for conflicts.
2. **External Relationships:** The principles establish clear guardrails to ensure close oversight and management of potential COIs and COCs. All disclosures of external financial interests and activities will be reviewed in the context of a Covered Person's role and responsibilities at MSK:
- **Conflicts of Commitment:** MSK will specify explicit thresholds pursuant to which a Covered Person's external activities will trigger the need for a comprehensive review by the COIC, department chairs, and the individual's supervisor (e.g., serving as a consultant for five or more companies).
 - **Board Service:** Service on the board of a for-profit entity by a Covered Person must be compatible with the interests of MSK and approved in advance by the COIC. MSK recognizes that while external board service raises COI issues, there are instances in which such service can be beneficial, and there may be circumstances in which such service will be allowed.

- o In reviewing requests to serve on a board of directors of a for-profit entity, the COIC will consider various factors such as a Covered Person's personal time commitment, engagement in or oversight of research or purchasing decisions that may be related to the proposed board service, involvement in patient care, and participation in institutional decisions that could be, or could appear to be, inappropriately influenced by the Covered Person's fiduciary duty to the external entity as its board member. The COIC will also consider whether such factors would or would not allow the Covered Person's conflict to be appropriately managed through firewalls, recusal from certain decisions, or other safeguards.
 - o This principle is not intended to prevent MSK from designating an MSK representative to serve on the board of an MSK spin-off in appropriate circumstances, as long as the MSK representative is not a Senior Vice President or above. Any compensation to the MSK representative will be required to be redirected to MSK.
 - **Service as a Corporate Executive:** Covered Persons will not hold executive officer roles (e.g., Chief Executive Officer, Chief Financial Officer, Chief Operating Officer, Chief Scientific Officer) in external for-profit biomedical, scientific, technology, or investment companies, or in any other company that does business with MSK, except under the circumstances described below. Covered Persons who wish to serve in an executive role at a for-profit company not encompassed by the exceptions below will be required to seek permission for a leave of absence from MSK for the period during which they will hold such executive role.
 - o **Spin-offs:** A Covered Person may serve as an executive of an early-stage start-up company that is formed by that Covered Person based on his or her specific area of research if MSK determines that such service is necessary for the start-up to advance its research program. The COIC may impose time limits on such executive roles (e.g., 12 months, until adequate funding is secured to hire an external executive officer).
 - **SABs and Consulting:** Service on scientific advisory boards (SABs) and consulting roles must be consistent with all COI and COC requirements.
3. **Disclosure and Transparency:** MSK will broaden the categories of staff members who are required to disclose outside activities and financial interests to MSK ("Covered Persons"). In addition, public transparency of such outside activities and financial interests will be enhanced. MSK Compliance will also conduct regular

and scheduled audits of disclosures to verify that complete and accurate disclosures have been made, both internally and externally.

- **Disclosure of Personal Financial Interests:** All Covered Persons must continue to report outside activities and financial interests to MSK fully and promptly. MSK will expand the definition of Covered Persons to include associate members of the medical staff, trainees, employees of certain administrative departments, employees with a management level of Vice President or above, and members of MSK committees with responsibility for oversight of clinical research, formulary, or other purchasing decisions. For clarity, MSK COI and COC policies will apply to all Covered Persons, including MSK's Senior Executive Officers — the Chief Executive Officer, Physician-in-Chief, Director of the Sloan Kettering Institute, Chief Financial Officer, and Chief Operating Officer.
- **Public Transparency:** In the interests of full and open disclosure, MSK will make publicly available, via its website, information about outside financial interests and activities of Covered Persons meeting certain criteria, including financial interests related to entities in the healthcare, biomedical, scientific, life sciences, and technology industries. This also includes financial interests in companies that make products used in patient care. The criteria for determining which financial interests will be disclosed on MSK's public website will be determined by the COIC.
- **Journal Disclosure:** MSK will continue to require clear and complete disclosure by faculty and staff of financial interests in publications or presentations of research related to those interests. This includes compliance with scientific journal requirements and other disclosure requirements regarding COIs.
 - **Key guideline:** When disclosure depends on the relevance of the financial interest to the research, and there is reasonable disagreement about that relevance, MSK expects faculty and staff to err on the side of disclosure.
- **Disclosure to MSK Personnel:** MSK will review and enhance its processes for requiring disclosure by Covered Persons of COIs to other faculty and staff working on research projects. MSK will also implement procedures to ensure that institutional COIs, arising from either institutional or Senior Executive Officers' interests in external companies, are properly disclosed to faculty and staff.
- **Improved Systems:** MSK will optimize and enhance systems used by Covered Persons to disclose outside financial interests to MSK. Such systems could include integration with additional tools (e.g., the Association of American Medical Colleges' Convey) or other appropriate technology that may be

developed in the future to serve as a single repository of all outside interests to facilitate harmonized disclosure to academic institutions, journals, professional associations, and government organizations.

- **Supervisory Engagement:** The COIC process for reviewing COIs and COCs will routinely involve the Covered Person's supervisors in a collaborative assessment of whether proposed outside activities, in the aggregate, detract from the Covered Person's commitment of effort to MSK. Together with the COIC, department chairs or other supervising institutional leaders will be responsible for reviewing and approving a Covered Person's outside activities in the context of the cumulative total of all outside commitments and the Covered Person's institutional responsibilities.
 - **Expanded Resources:** MSK will develop enhanced tools, improved training, templates, and other educational resources to support faculty and staff compliance with internal and external disclosure requirements, including disclosures to journals. MSK will further seek opportunities to work with external parties to develop harmonized standards for disclosures of financial interests in publications and presentations of research.
 - **Mechanisms for Raising Concerns:** MSK will establish, and frequently publicize, mechanisms for employees to raise questions and concerns about conflicts-related policies and procedures. MSK will emphasize to the MSK community that retaliation for concerns reported in good faith is unacceptable and will not be tolerated.
4. **Office of Technology Development (OTD):** Oversight of OTD licensing agreements will be enhanced in appropriate circumstances, and channels of communication between OTD and groups involved in conflicts management will be bolstered.
- **Review of Licensing Agreements:** MSK will establish a mechanism for the review of licensing agreements prior to execution by personnel external to OTD to ensure business terms are appropriate and in MSK's best interests. Consideration will also be given to potential COIs arising from the agreement and reputational impact on MSK.
 - **Notification of Licensing Negotiations:** OTD will notify MSK Compliance and the COIC prior to the commencement of licensing negotiations in cases where an MSK employee or Board member has a known interest in the outside entity in order to ensure that a management plan is implemented in a timely fashion. Relatedly, channels of communication will be strengthened among OTD, the COIC, MSK Compliance, and the Office of General Counsel to ensure that information about the roles of faculty and Board members in MSK spin-offs is available in a prompt fashion to facilitate timely completion of management plans and related safeguards.

5. **Research:** The following approved principles will apply broadly to the continuum of basic, translational, and clinical research. Researchers' financial interests will be reviewed by the COIC and managed where applicable; management will include, at minimum, full disclosure of financial interests to laboratory and research staff, research participants (if any), and in presentations and publications.

Additional specificity and safeguards related to COIs in research are outlined below:

- **Clinical Research:**
 - A faculty member will not be permitted to serve as principal investigator (PI) or co-PI in any interventional human subjects research sponsored by or related to a company in which the faculty member has significant financial interests (exceeding \$25,000 in public companies or any equity in private companies in the previous 12-month period) absent compelling circumstances, which will be determined by the COIC. If permitted, the research will be conducted under robust management strategies to protect the rights and welfare of human research subjects as well as the objectivity and integrity of the research. If a conflicted researcher is permitted to remain engaged in research under COI management, the COIC will define additional limits on any external compensation that may be received during the course of a research study, in addition to other management strategies.
 - There are additional types of financial interests that would preclude a Covered Person from serving as PI or co-PI (e.g., serving as an executive or board member of a company supporting the research, being an inventor of the intellectual property under evaluation in the research).
 - MSK will not conduct interventional human subjects research at MSK when MSK has a financial interest in the product, technology, or company being evaluated absent compelling circumstances, which will be determined by the COIC.
- **Permissible Exceptions:** These approved principles are not intended to prohibit MSK from conducting interventional human subjects research that evaluates products or technologies invented at MSK, and in which MSK has a financial interest, as long as such research satisfies the "compelling circumstances" test set forth below and appropriate safeguards are established to protect research participants and to mitigate risk of bias. These principles are also not intended to apply to non-interventional research involving human subjects (e.g., retrospective studies analyzing clinical data) or to preclinical research.

- Exceptions to the principles stated above will be granted only when compelling circumstances exist, taking into consideration the best interests of the patients and the following factors, including:
 - whether MSK is uniquely qualified as a study site (e.g., special facilities and equipment, unique patient population, unique expertise of MSK research and clinical staff);
 - the degree of risk to human subjects posed by the interventional research protocol;
 - whether the nature and magnitude of the financial interest, and the extent to which the research is related to the interest, could directly and substantially affect the research, or vice versa;
 - whether the risk of bias can be effectively managed (e.g., limits on the conflicted investigator's role, additional oversight or monitoring, disclosure to research participants of financial interests of investigators and/or MSK); and
 - the degree of risk to MSK's reputation.
- **Disclosure to Others Involved in Research:** Covered Persons with a COI must disclose to others working in the lab, or who are collaborating on a research project, any outside financial interest in a healthcare, biomedical, scientific, or technology company that could affect or be affected by the research being conducted; the nature of any sponsored awards or other research support received from such companies, including its specific scope of work and the time and effort allocations applicable to those persons; and financial interests to the thesis committees (e.g., ACE, TPE, Special Committees) of any graduate students working in the lab.
- **Standing Committee:** The COIC will determine whether the risk of bias in research data resulting from conflicts of interest will be mitigated by establishing periodic reviews by a standing committee composed of representative faculty and staff. Any requirement for this level of review will be included in the terms of the management plan.
- **Ombudsperson:** MSK will consider the appointment of a research ombudsperson to serve as an objective resource to whom concerns can be addressed confidentially. Beyond that, researchers, lab members, and collaborators will be invited to direct any concerns about the supervision or direction of their research to an MSK faculty mentor external to the research team or the laboratory, or to the MSK Compliance office.
- **Financial Interests of Senior Management:** MSK will implement a management plan in each instance in which a Senior Executive Officer has a financial interest in a company sponsoring research at MSK (or decline the

research opportunity). A consistent process will be implemented to ensure that such interests are reported to the Institutional Review Board (IRB).

6. **Income Sharing:** As required by law and policy, MSK must share income that it receives from the licensing of intellectual property developed at MSK with individual inventors of that intellectual property:

- **Defined Contribution:** Distribution of institutional income will be related to the person's "personal and identifiable intellectual contribution" to the income-generating intellectual property. Employees will not receive founder's shares or institutional income for the execution of their regular job duties, including the structuring of a licensing agreement, the provision of patient care, or support from a core facility.
- **Multiple Inventors:** If there are multiple inventors, inventors may decide, among themselves, their respective shares of the income. If inventors cannot agree on a proposed division of income, the distribution will be determined by consultation among the Chief Executive Officer, the inventors' department head(s), and staff from the OTD and the OGC. MSK staff overseeing the allocation of remuneration will invoke this adjudicative process for any proposed distribution that appears not to be based on an employee's personal and identifiable intellectual contributions.
- **Distributing Income:** To reduce the actual or perceived risk that institutional income may be distributed to individuals who have not made personal and identifiable intellectual contributions to the income-generating intellectual property, MSK will discourage employees who receive institutional income from redistributing that income to other MSK employees. MSK may compensate, as appropriate, employees who have not made personal and identifiable intellectual contributions to the income-generating intellectual property, but who have otherwise provided exceptional effort toward the development of the intellectual property, through MSK's existing compensation and bonus systems. However, "personal and identifiable intellectual contributions" will not include data, biospecimens, know-how, and similar contributions or products made in the regular course of business by MSK employees performing their assigned job duties.
- **Reviewing Distributed Income:** For clarity, MSK employees who make "personal and identifiable intellectual contributions" that exceed the products of their regular job duties and that result in the creation of new intellectual property may receive institutional income consistent with the rules outlined above. MSK will continue to consider allocating a portion of institutional income resulting from the use of institutional resources, on a case-by-case basis and depending on the circumstances, to the department(s) or academic unit(s) where the work was done to create the resource.

7. **Monitoring, Auditing, and Compliance:** MSK will establish a robust process for monitoring and auditing compliance with COI and COC policies, including compliance with the terms of management plans.
- **Ensuring Accuracy:** MSK will utilize external and/or publicly available information against which to compare a Covered Person's disclosures to MSK.
 - **Audits:** MSK will conduct regular and scheduled audits using both a risk-based and random approach to ensure accuracy of reporting to MSK of outside activities and financial interests and to verify complete and accurate disclosures in publications and presentations and compliance with any management plans. This would include review of relevant documentation (e.g., publications, presentations, research consent forms, notifications to laboratory members and research staff and collaborators on research projects) and interviews with persons subject to the management plan and representative colleagues, research staff, and/or lab team members.
 - **Management Plans:** MSK will also undertake a review of the terms of management plans to ensure they are sufficiently broad in scope yet detailed enough that Covered Persons understand what is required, and provide counseling to ensure the boundaries of recusal are appropriately understood and to help strategize methods for operationalizing firewalls.
 - **Emphasis on Compliance:** Senior executives will regularly and publicly communicate the importance of compliant practices, including an emphasis on rigorous oversight of and compliance with COI policies.
 - **Campaigns:** MSK will consider launching periodic institutional initiatives to raise awareness of the importance of ethics, accountability, and compliance. A specific initiative will be focused on raising awareness of policies and procedures relating to COIs, COCs, and interactions with external parties and encouraging open discussion about concerns.
 - **Periodic Surveys:** MSK will continue to conduct periodic annual culture surveys seeking input from employees on a confidential basis regarding the institution's focus on compliance, including but not limited to whether COIs are viewed as being appropriately managed and employees' level of comfort in raising concerns about COI issues. MSK will consider publicizing the results of the survey to the MSK community.
 - **Sanctions:** Failure to disclose financial interests internally or externally, or to comply with a management plan or plans, represents a violation of MSK policy and may subject the Covered Person to discipline, up to and including termination of employment.